UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 23-8008

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
The Honorable Robert B. Kugler, No. 19-2875

ECONOMIC LOSS CLASS PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' PETITIONS FOR PERMISSION TO APPEAL PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 23(f)

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CORPORATE DISCLOSURE STATEMENTS

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit Local Appellate Rule 26.1.1, Plaintiff-Respondents hereby make the following disclosures:

VRM MSP Recovery Partners, LLC, a Delaware limited liability company, is the sole member of Plaintiff/Respondent, MSP Recovery Claims, Series LLC. The members of VRM MSP Recovery Partners, LLC are (i) Virage Recovery Master LP, a Delaware limited partnership, and (ii) Series MRCS, a designated series of MDA, Series LLC, a Delaware series limited liability company. No publicly held companies owns 10% or more of MSP Recovery Claims, Series LLC's stock.

Maine Automobile Dealers Association, Inc. Insurance Trust has no parent corporation and no publicly held corporation owns 10 percent or more of its stock. However, as a Multiple Employer Welfare Arrangement, Maine Automobile Dealers Association, Inc. Insurance Trust has a sponsor (the Maine Automobile Dealers Association).

Dated: March 23, 2023

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Plaintiff-Respondents ("Plaintiffs") submit this opposition on behalf of the economic loss ("EL") consumer and third-party payor ("TPP") class plaintiffs.[1]

I. INTRODUCTION

This MDL involves one the largest prescription drug recalls in history for valsartan, a generic blood pressure drug. Defendant-Petitioners ("Defendants") manufactured and sold adulterated valsartan-containing drugs ("VCDs"). Defendants flagrantly violated current Good Manufacturing Practices ("cGMPs") when manufacturing these products, which resulted in the contamination of VCDs with "high potency mutagenic carcinogens"[2] rendering them economically worthless. The EL class plaintiffs seek their money back for these worthless, contaminated drugs; they do not allege personal injuries or product-liability claims.

Rule 23(a)'s elements are not at issue here. Neither is ascertainability. Defendants' petitions solely focus on the Rule 23(b)(3) manageability of certified subclasses involving more than one party and more than one state's law.

Defendants ignore that the MDL Court did the necessary work of analyzing, confirming, and modifying Plaintiffs' proposed subclasses, consistent with previous Third Circuit guidance, to ensure that the case proceeds with manageable subclasses that account for legal and potential factual variability. The MDL Court, fully aware

[1] The medical monitoring ("MM") class plaintiffs write separately, as their actions implicate different issues.
[2] https://www.fda.gov/media/85885/download (so defining nitrosamines).

of the tools available for managing complex litigation, has never said it intends to try an omnibus class case. The imaginary specter of a giant "mega-trial" is Defendants' invention. Their unsupported speculation about what the future might hold is not a legitimate basis for Rule 23(f) relief and their petitions should be denied.

II. STATEMENT OF THE CASE

Relevant Procedural Background. On February 14, 2019, the Joint Panel on Multidistrict Litigation (JPML) created this MDL, and assigned it to the District Court ("District" or "MDL" Court), to coordinate all actions alleging that "plaintiffs purchased or used generic formulations of valsartan medications containing the nitrosamine impurities NDMA or NDEA." D.E. 229, at 2.

Facts. The class-action arm of this MDL involves a single generic drug, valsartan, which was contaminated with unapproved, undisclosed, carcinogenic nitrosamines, rendering them adulterated.[3] Valsartan is the generic version of the brand name hypertension drug DIOVAN® ("Diovan") and a related valsartan combination product called EXFORGE® ("Exforge"). Common evidence demonstrates that generic drug Manufacturer Defendants made critical changes to the manufacturing processes for their VCDs. In implementing these process changes, they systematically violated cGMPs in not conducting the necessary quality

[3] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-huahai-pharmaceutical-566685-11292018 (FDA Nov. 29, 2018 Warning Letter).

assurance activities, which would have prevented this contaminated drug from being sold in the United States. *See supra* fn.3.

All Defendants had an obligation to ensure that the VCDs they sold were the generic equivalent, or in layman's terms the "same," in all material respects, as the branded Diovan and Exforge, and this obligation extended down the supply chain. But their VCDs were not the same. Defendants' VCDs contained genotoxic contaminants that were not approved by the FDA for inclusion in any Defendant's VCD. The FDA identified "significant" cGMP failures related to the manufacturing processes, and the resulting adulteration of these VCDs. *See supra* fn.3.

The only real dispute between the parties lies with how the EL Plaintiffs set about to determine their damages for their purchase of these products. Plaintiffs proffered the expert testimony of Dr. Rena Conti to provide class-wide evidence of economic injury, and damages. Dr. Conti opined that when the Class Members purchased the economically worthless VCDs, they did so with the expectation that the drugs were what they were represented to be, not contaminated with any harmful substances, and had been produced in accordance with cGMPs. D.E. 1748 at 68-69. Dr. Conti opined that there is no legitimate supply curve for prescription drugs which are manufactured in such a way that a manufacturer cannot ensure their safety and

quality. *Id.* Thus, there is no economically determinable price for noncompliant drugs.[4]

The Class Certification Opinion. After a year of briefing which included dozens of briefs, dozens of expert reports, hundreds of exhibits, and months of discovery, the MDL Court issued its ruling on Class Certification. Heeding the Third Circuit's call to conduct a "thorough-going, rigorous class certification analysis" as required by *Mielo v. Steak 'N Shake Operations, Inc.*, 897 F.3d 467 (3d Cir. 2018), the MDL Court found that there was "singularly pleaded conduct" which applied "unilaterally to each consumer plaintiff in each subclass because each purchased the contaminated VCDs." D.E. 2261 at 22. The MDL Court also took a "practical" approach and confirmed that the EL Plaintiffs' proposed subclasses "aptly" mapped the state law variation and factual variability. *Id.*

Post-Certification Case Management. Following the above ruling, the MDL Court set a hearing in late March to address Defendants' Motion to Stay and related case management issues. The parties have agreed that class notice should not be issued pending a determination on Defendants' Rule 23(f) petitions.

[4] Dr. Conti's valuation does not require any analysis of whether, or at what levels, NDMA/NDEA has been shown to cause cancer. General causation plays no role in the Plaintiffs' EL class actions because it is not an element of their state law claims. To the extent materiality of the wrongdoing need be shown, the recall of VCDs due to "unacceptable carcinogenic risk" (D.E. 2057-10) is more than sufficient.

III. STANDARD OF REVIEW

This Court may deny a Rule 23(f) petition "on the basis of any consideration the court of appeals finds persuasive." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 165 (3d Cir. 2001). This Circuit only considers a "narrow yet flexible, set of considerations . . . in granting a Rule 23(f) petition." *Byrd v. Aaron's Inc.*, 784 F.3d 154, 171-72 (3d Cir. 2015). Based on Defendants' arguments, those are "when class certification risks placing inordinate ... pressure on defendants to settle"; "when an appeal implicates novel or unsettled questions of law"; "when the district court's class certification determination was erroneous"; or "when the appeal might facilitate development of the law on class certification." *Laudato v. EQT Corp.*, 23 F.4th 256, 258 (3d Cir. 2022). None apply here.

This Court reviews class certification orders for "abuse of discretion" which only exists if "the district court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law, or an improper application of law to fact." *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 358 (3d Cir. 2015). Under the "clearly erroneous" standard, an appellate court must "accept the ultimate factual determination of the fact-finder unless that determination either (1) is completely devoid of minimum evidentiary support displaying some hue of credibility, or (2) bears no rational relationship to the supportive evidentiary data." *Giles v. Kearney,* 571 F.3d 318, 322 (3d Cir. 2009).

IV. REASONS TO DENY THE PETITION

A. The MDL Court's Pragmatic Approach Comports With Rule 23(b)(3)

Defendants' invocation of a single class mega-trial involving "428 different products, made and sold by 28 different defendants" (Pet. at 1, 12) is a fantasy. Different dosages, strengths, or distribution codes of the same contaminated generic product are not "different products," and all raise the same issues on the economic loss claims. *Boley v. Univ. H. Servs., Inc.*, 36 F.3 4th 124, 132 (3d Cir. 2022) (rejecting notion that certified class alleged "thirty-seven separate claims challenging thirty-seven separate investment options").

The MDL Court never suggested it intends to conduct a single class mega-trial against all Defendants simultaneously. Quite the opposite. The MDL Court had indicated prior to certification that the first trial would consist of TPP economic loss claims against only three defendants–ZHP, which manufactured and sold contaminated valsartan active pharmaceutical ingredient ("API") and finished dose pills, and Teva and Torrent, two finished-dose manufacturers that purchased and incorporated the contaminated API manufactured by ZHP into their own VCDs.

The MDL Court has the discretion to try (or prepare for trial and remand) a series of subclasses' claims, again organized by plaintiff type (consumer or TPP) and defendant group. In doing so, the MDL Court can apply its intimate familiarity with the claims and facts garnered through four years of careful oversight of this

litigation. No one is in a better position to steer these class claims through, however many trials it takes, than the MDL Court. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 310 (3d Cir. 2008) ("The trial court, well-positioned to decide which facts and legal arguments are most important to each Rule 23 requirement, possesses broad discretion to control proceedings and frame issues for consideration under Rule 23."). This is even more compelling in an MDL.

Defendants' current (incorrect) arguments are belied by their past statements. Two years ago, Defendants insisted that all class certification issues be heard in a single *omnibus* motion. Defendants said doing so **"provides flexibility for structuring different trial plans.**" *See* D.E. 393 (emphasis added). Defendants added: "**Any Defendant-specific issues related to certification could still be addressed in this context. . . [S]hould certification be granted, Plaintiffs could still seek to sever a specific subclass or issue class for a discrete trial. An omnibus motion would thus increase efficiency while maximizing flexibility**." *Id.* (emphasis added). Defendants should be estopped from contesting the very approach they themselves argued Plaintiffs were required to undertake.

The MDL Court accepted Defendants' *omnibus* class certification proposal, and is in the process of deciding, under its discretionary case management authority, how to structure trials upon completion of class notice and opt-out periods. This pragmatic approach—in an MDL context no less, where the JPML expressly

consolidated all class cases before the MDL Court to tackle all pre-trial matters, including class certification, so as to eliminate inconsistent rulings—is consistent with the law of this Circuit and the teachings of the Federal Judicial Center.

B. Subclasses Are Superior to the Alternative

Defendants overlook that manageability is just one component of Rule 23(b)(3)'s superiority analysis. The size of a class (or classes) is no reason to deny certification. *See Kelly v. RealPage Inc.*, 47 F.4th 202, 224 (3d Cir. 2022).

Manageability, like superiority, is also inherently comparative. The alternative is thousands of near-identical individual litigations with potentially divergent outcomes across the country. Trying each such claim individually would be far more burdensome and costly than managing discrete subclasses. And having thousands of costly individual cases strewn across the country would be far less efficient and economically reasonable than an orderly series of subclass trials.

C. There Is No Manifest Error in Creating Subclasses

The MDL Court and Plaintiffs did the required work to establish manageability and predominance: cogently grouping states based on variations of state law and accounting for the facts and law of the case. *Compare In re Prudential Ins. Co. Am. Sales Pracs. Litig. Agent Actions*, 148 F.3d 283, 315 (3d Cir. 2001) (approving "series of charts setting forth comprehensive analyses of the various states' laws"), *with Grandalski v. Quest Diagnostics, Inc.*, 767 F.3d 175, 183-84 (3d

Cir. 2014) (chiding plaintiffs for failing to provide "virtually any" analysis but nevertheless endorsing multistate class certifications where appropriate).

Plaintiffs provided meticulous justification based on the facts and law of the case for their proposed state law groupings, *see* D.E. 17147-1, 1747-2, D.E. 2057-274, 2057-275, 2057-276, and the MDL Court "researched and reviewed the required elements of plaintiffs' five major claims in each proposed jurisdiction" and re-organized the state law groupings as it deemed appropriate. *See* D.E. 2261 at 21. The MDL Court found that EL Plaintiffs made a "creditable showing" that groupings did not present "insuperable obstacles" to trial management. *See In re Asbestos Sch. Litig.*, 789 F.2d 996 (3d Cir. 1986) (en banc) (affirming Rule 23(b)(3) certification in case involving ~14,000 schools asserting various state common law class claims against ~50 defendants at all levels of supply chain).

1. Defendants' Litany of Purported Individualized "Fact Issues" Is Speculative and Unsupported

Defendants speculate about "individualized questions of defect, materiality, reliance, causation, injury and damages" (Mfr. Pet. at 14) with virtually no discussion and with no demonstration that any of these "issues" are of real concern in this case.

The supposed "individual issues" Defendants raise are not individual issues at all. It is well settled that "[a]n individual question is one where members of a proposed class will need to present evidence that varies from member to member,

while a common question is one where the same evidence will suffice for each member to make a prima facie showing or the issue is susceptible to generalized, class-wide proof." *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, (2016).

The MDL Court properly found that Plaintiffs demonstrated that they could prove the elements of their state law claims with common evidence predicated on undisputed facts. Indeed, Defendants do not dispute that (i) their VCDs were contaminated as a result of manufacturing processes that created genotoxic carcinogens NDMA/NDEA in VCDs they sold during the class period(s) (they acknowledge the NDMA and NDEA persisted into the finished dose); (ii) those drugs were recalled due to the "unacceptable carcinogenic risk" *(see* D.E. 2057-10)[5]; (iii) they warranted that their VCDs were FDA-approved Orange Book A/B rated generic equivalents of the respective brand name drug; and (iv) that consumers would not have been able to purchase their VCDs had the facts been known regarding their contamination (a fact Defendants' own experts conceded). Defendants ignore these liability facts, speculating instead that some universe of facts not in evidence would show that common issues might not predominate.[6]

[5] Not all generic valsartan was contaminated. Defendants' contaminated VCDs represented about half of the market.

[6] Defendants and their experts cynically posit that some consumers *may* have wanted to ingest probable human carcinogens, and therefore their adulterated VCDs may have held some "value." But Defendants have offered no empirical evidence to support that hypothesis. Their experts were appropriately struck by the MDL Court

Plaintiffs' burden on class certification was to demonstrate predominance by showing that common issues were susceptible to common proof, not to try the case and affirmatively respond to any and all hypothetical defenses. "[S]peculation and surmise" should not "tip the decisional scales in a class certification ruling." *See Bridging Communities Inc. v. Top Flite Fin. Inc.*, 843 F.3d 1119, 1125 (6th Cir. 2016).

2. The MDL Court Did Not Err When Finding Common Issues Predominated

A review of the elements and evidence demonstrates Plaintiffs met their burden. The Court correctly concluded that the breach and causation elements of the warranty- and fraud-based claims do not implicate any individual issues at all, let alone issues that would predominate in comparison to the far greater number and significance of common issues. Defendants also reference materiality–but gloss over the fact that materiality need not be proven at class certification. What is relevant at class certification for the materiality inquiry is whether it presents common issues. *Amgen Inc. v. Ct. Retirement Plans & Trust Funds*, 568 U.S. 455, 469 (2013). In the class certification context, plaintiffs asserting fraud claims in

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because none provided support for the novel proposition that a consumer would choose to purchase an adulterated drug contaminated with an unapproved carcinogenic genotoxin (which is illegal to sell) as opposed to uncontaminated generic valsartan that was available at the same time.

situations where the claims are predicated on a failure to disclose pertinent quality and purity information (e.g., their product contained NDMA and was not the same as the approved brand Diovan) need not demonstrate "positive proof of reliance." *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

As to reliance and causation, Defendants point solely to a purported variance among state consumer protection acts concerning the deceptive or reliance-inducing acts (Mfr. Pet. at 14). The substantive actionable "deceptive act" here is the sale of contaminated and adulterated prescription pharmaceuticals represented as the approved version of the drug. Contrary to Defendants' suggestion that differences in state law will swamp common issues, many states modeled their consumer protection statutes on the Federal Trade Commission Act, including rules on what conduct constitutes actionable "deception." *See* D.E. 1748-22. And in demonstrating that common evidence can be used to prove the existence of a deceptive act, Plaintiffs noted that the VCDs were contaminated with NDMA and NDEA, were considered adulterated by the FDA, and were sold to Plaintiffs without disclosure of the contamination or cGMP failures. Defendants cannot and do not dispute these common facts.

Nor can Defendants dispute that those deceptive acts were relied on *en masse* by purchasers and caused their economic injuries. The MDL Court has already made a preliminary finding that the "very naming of the drug as valsartan or valsartan-

containing" and its sale as a prescription drug would constitute a warranty or representation. As the Court acknowledged, the nature of the generic pharmaceutical market results in consumers having "had no choice but to rely" on Defendants' representations and warranties, causing them economic injuries in the event they paid any amount of money for an economically worthless product (*see infra*). D.E. 775, at 14.

D. Defendants' Oblique Challenge to EL Plaintiffs' Damages Theory and Modeling Does Not Establish Any Manifest Error

The Court should reject Defendants' argument as to damages for at least three reasons: (1) it is an improper challenge to the MDL Court's *Daubert* ruling, and an inappropriate basis for requesting 23(f) review; (2) it does not relate to the fact of injury, just the quantity of damage; and (3) potential individualized damages issues do not defeat certification.

1. Defendants Purposefully Conflate Injury-in-Fact with Quantification of Damages

Damages have two distinct aspects: the fact of damage and the measure/amount of damage. *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 305 (3d Cir. 2016). A plaintiff satisfies the predominance requirement by providing a reliable model that delineates class-wide injury in fact, as occurred in this case. More individualized damages issues (such as the ones raised by Defendants) do not defeat class certification. "[D]ifferences among the class members concerning the

precise damages they suffered . . . are of no consequence in determining whether there are common questions concerning liability." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 967 F.3d 264, 272 (3d Cir. 2020). Denying class certification based on a finding of individualized damages would "amount [] to an abuse of discretion." *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 375 (3d Cir. 2015).

Defendants conflate the two damages concepts when making their argument. They do not take issue with the fact of injury (*i.e.,* that class members purchased the contaminated drugs that were recalled when the contamination was discovered).[7] Defendants' arguments instead relate to the measure of damages.

As discussed *supra* in Part II, Dr. Conti applied principles of economics to calculate class-wide damages at the point of sale. Because the adulterated VCDs could not lawfully be sold, Dr. Conti determined that there was no legitimate supply curve, which, according to well-accepted economic theory, means that there is no determinable market price. Thus, the VCDs were economically worthless and held

[7] Defendants point to the FDA's statement that patients should not discontinue their use of contaminated valsartan pending their physician changing their medication. Mfr. Pet. at 15. This was a temporary safety measure only, and simply a recognition that abrupt discontinuation could lead to stroke or death, not an endorsement of the safety of the contaminated drugs.

zero value. Dr. Conti then set out to calculate aggregated class-wide damages. The MDL Court found that Dr. Conti's methodology was sufficiently reliable.[8]

2. The MDL Court Fulfilled Its Responsibilities Under *Daubert* and Rule 23

Defendants misuse the MDL Court's statement that Rule 23(b)(3) was not satisfied through "acceptance of either [side's] proposed economic loss theories" to assert an abdication of the court's responsibilities under Rule 23. Mfr. Pet. at 17. Not so. The MDL Court explicitly found both Dr. Conti and Defendants' damages expert qualified and their opinions reliable, and considered both in reaching its ruling. D.E. 2261 at 89. The MDL Court appropriately acted as a "gatekeeper" and found that both damages experts can present their damages models to a jury.

E. No "Inordinate Settlement Pressure" Exists

Defendants' perfunctory reference to the Rule 23(f) "inordinate settlement pressure" factor goes nowhere. Defendants' keyword-search for "settlement" in four years' worth of bi-weekly conference transcripts, finding a few statements consistent with Federal Rule of Civil Procedure 16, is tantamount to adding improper parole evidence to their petition, which is meant to challenge only the Court's order. Defendants also boldly cite the MDL Court's *quotation* of Rule 23(b)(3) superiority

[8] *See also Blue Cross Blue Shield Ass'n et al. v. GlaxoSmithKline LLC*, No. 13cv4663, 2019 WL 4751883, at *8 (E.D. Pa. Sept. 30, 2019) (finding in near-identical adulterated drug case that "Dr. Conti has [] provided a sufficient reliable basis and methodology for her expert opinion").

jurisprudence. D.E. 2261 at 41. They fail to demonstrate any improper pressure. *See Manual for Complex Litig. (Fourth)* § 21.28 ("interlocutory review should not be granted unless" order is "death knell," is tantamount "to an abuse of discretion," or involves unique issue "otherwise likely to escape review").

F. "General Causation" Plays No Role Here, and Is Beyond the Scope of Rule 23(f) Jurisdiction

The order at issue certified EL class claims seeking only *economic* damages. Plaintiffs do not seek personal-injury damages, and do not allege product-liability claims (e.g., failure to warn). Plaintiffs seek to recover monies paid for contaminated and thus adulterated VCDs, which no customer would have purchased but for the warranties, a point confirmed by Defendants' corporate designees and experts. *See* D.E. 2057 at 14. Because their damages do not depend on the degree of their exposure, purported variations in Consumer EL Plaintiffs' exposure to NDMA or NDEA (*see, e.g.,* Mfr. Pet. at 2, 17) have zero bearing on their economic losses. The dosage of VCDs purchased, the amount of VCDs ingested, or how much NDMA/NDEA were ingested by consumers does not change the fact that each class member paid for economically worthless drugs and suffered economic harm at the point of sale.

Nevertheless, Defendants seek to collaterally attack the MDL Court's Daubert rulings on general causation experts by referencing a wholly distinguishable non-

VCD case,[9] and falsely implying that their VCDs contained insignificant levels of NDMA or NDEA (a characterization Defendants' own consultants and employees disagreed with in internal exchanges produced in discovery). Not only does this argument have no place in this petition, it ignores the indisputable fact that these levels were unapproved, and that Defendants themselves publicly stated they were "unacceptable" at the time of the recall. D.E. 2057-10.

But these factual quibbles are of no moment for this petition. Because the EL Class Plaintiffs' claims do not rely or turn on physical injury, or last years' general causation *Daubert* rulings have no direct bearing on EL Class Plaintiffs' claims, and therefore are beyond the narrow jurisdictional confines of the current Rule 23(f) petitions. *See In re Citizens Bank, N.A.*, 15 F.4th 607, 614 (3d Cir. 2021); *McKowan Lowe & Co. v. Jasmine, Ltd.,* 295 F.3d 380, 390 (3d Cir. 2002).

G. Retailers' and Wholesalers' Additional Arguments Lack Merit

Retailers and Wholesalers make the same manageability arguments as the Manufacturers, adding nothing new. Their other arguments also fail to justify Rule 23(f) review.

[9] The *Zantac* MDL (*see* Mfr. Pet. at 8 n.1) ruling is inapposite. Nitrosamines in Zantac were a *degradation* impurity (created after manufacture); here, all parties and the FDA agree nitrosamines were a *process* impurity (created during manufacture). The *Zantac* court believed the class claims there turned on the levels of NDMA in Zantac, and found that plaintiffs' experts were unable to reliably establish those levels as a threshold. The levels of contamination here were established by the manufacturer defendants' and FDA testing.

Retailers misconstrue *Comcast Corp. v. Behrend*, 569 U.S. 27 (2013). *See* Retailer Pet. at 15. *Comcast* merely requires that a plaintiff's aggregate damages model "match[] a viable theory of liability." *In re Suboxone*, 967 F.3d at 270. EL Plaintiffs allege that they purchased adulterated VCDs, giving the right to recover economic damages under various states' laws. To estimate damages for Defendants' misconduct under those states' laws, Dr. Conti explains there is no "legitimate supply curve" for adulterated drugs because federal law (and analogous state laws) prohibit their sale. *See, e.g.*, 21 U.S.C. §§ 331, 351. This is consistent with the record in this case. Defendants and defense experts agree that they cannot and do not sell or dispense adulterated drugs. D.E. 2057 at 14-15, 35-36. Dr. Conti uses reputable third-party data from IQVIA to calculate the class-wide aggregate economic harm at the point of sale.[10] She further segmented her damages estimates by Defendant (whether manufacturer, wholesaler, or retailer) by state and by theory. This comports with *Comcast*.

Retailers' plea that they cannot be "strictly liable" as pharmacies (Retailer Pet. at 5) also rings hollow. EL Plaintiffs do not allege strict liability claims.

Also lacking merit is Retailers' assertion of manifest error through new, purported state law "variations" (Retailer Pet. at 8). Different limitations periods

[10] Defendants' corporate witnesses and experts admitted that IQVIA data is the gold standard. *See, e.g.*, D.E. at 7.

(*id.* at 8) are immaterial because class actions were filed mere weeks after the initial recalls in 2018. No Defendant even asserts a statute of limitations defense. Similarly, Retailers fail to show how purportedly different definitions of "merchantability" (*id.* at 8) would be meaningful here (Defendants and their experts conceded that the adulterated VCDs could not lawfully be sold), or beyond the ability of jury instructions or questionnaires to address. Regardless, minor variation or differences do "not defeat commonality and predominance." *In re Asbestos*, 789 F.2d at 1010; *Sullivan v. DB Investments, Inc.*, 667 F.3d 273, 301 (3d Cir. 2011) (en banc).

Wholesalers' contention that every class member must prove Article III standing at the class certification stage (Wholesaler Pet. at 9) runs counter to the black-letter law of this Circuit and every other. *See, e.g.*, *Carolina Youth Action Proj. v. Wilson*, -- F.4th -- , 2023 WL 2147305, at *4 (4th Cir. Feb. 22, 2023) (standing is justiciability concept that does not have "anything to do with class certification"); *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 68-81 (9th Cir. 2022) (en banc) (Article III standing for all class members not required at class certification); *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 362 (3d Cir. 2015) ("We now squarely hold that unnamed, putative class members need not establish Article III standing.").

Wholesalers also incorrectly demand that Plaintiffs must trace and prove each class member's injury now (Wholesaler Pet. at 10). EL Plaintiffs' burden at class certification is not to prove the case, but to show that impact can be demonstrated at trial through common evidence. *In re Hydrogen Peroxide*, 552 F.3d at 311-12. EL Plaintiffs demonstrated that the same common evidence (e.g., Defendants' transactional records) can prove which Defendants sold which VCDs to which class members. Nothing more was required for class certification. *Id.*

V. CONCLUSION

This Court should decline to take up Defendants' Rule 23(f) petitions with regard to the EL class actions. Defendants' conclusory arguments are not sufficient to overcome the MDL Court's careful and appropriate consideration of the record in ordering class certification.

Dated: March 23, 2023

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LOCAL APPELLATE RULE 46.1 CERTIFICATION

I hereby certify, pursuant to L.A.R. 46.1, that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

Dated: March 23, 2023

/s/ Ruben Honik
Ruben Honik

CERTIFICATE OF COMPLIANCE, IDENTICAL COPIES, AND VIRUS SCAN

I hereby certify that:

1. This response complies with the type-volume limitation of Fed. R. App. P. 5(c) because it contains 4,918 words, as determined by Microsoft Word, the word processing software used to prepare this petition.

2. This response also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman size 14 font.

3. The text of the electronic version of this response filed via CM/ECF is identical to the text of the paper copies, if any, filed with the Court.

4. The electronic version of this petition was virus checked using Microsoft Defender 4.18.23205.7 and no virus was detected.

Dated: March 23, 2023

/s/ Ruben Honik
Ruben Honik

CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2023, I electronically filed the foregoing with the Clerk of the United States Court of Appeals for the Third Circuit through the CM/ECF system. A true and correct copy was sent via electronic mail per agreement of the underlying parties to all counsel of record.

Dated: March 23, 2023

/s/ Ruben Honik
Ruben Honik